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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,446

10/10/2007

Gabor Forgacs

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1657

NOTIFICATION DATE

DELIVERY MODE

08/09/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/590,446	<b>Applicant(s)</b> FORGACS ET AL.	
	<b>Examiner</b> Kailash C. Srivastava	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-17 and 52-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-9, 11-17 and 52-66 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

1. Applicants' Preliminary Amendment filed 24 August 2006 is acknowledged and has been entered.

### **Informal Matters**

2. Note that the correct Serial Number for instant Application currently under prosecution at the United States Patent and Trademark Office (i.e., USPTO) is 10/590,446. Please ensure that the correct U.S. Serial Number (i.e., 10/590,446) for the instant application is cited in all future correspondence with this Office.

3. The assigned Art Unit location for the instant application (i.e., 10/590,446) at the USPTO is 1657. To aid in correlating any papers for this application (i.e., 10/10/590,446), all further correspondence regarding this application (i.e., 10/10/590,446) should be directed to Art Unit 1657.

4. The assigned Examiner to the instant application (i.e., 10/10/590,446) at the USPTO is Kailash C. Srivastava. To aid in correlating any papers for this application, all further correspondence regarding this application (i.e., 10/10/590,446) should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

### **Claims Status**

5. According to the Amended Claims set filed 24 August 2006, the current Claims status is as follows:

⌚ Claims 10 and 18-51 have been cancelled; and

⌚ Claims 1-9, 11-17 and 52-66 are currently pending.

### **Election /Restriction**

6. Restriction to one of the following inventions is required under 35 U.S.C. §121 and §372.

7. This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1 and 37 C.F.R. §1.475.

In accordance with PCT rules cited *supra*, applicant is required, in reply to the instant Office Action, to select a single invention to which the claims must be restricted.

- Group I, consisting of claims 1, 5-9, and 11-17 drawn to a method to produce a plurality of fused cell aggregates forming a three-dimensional structure, wherein a layer of matrix is deposited on a substrate; at least one aggregate of plurality of cells is embedded in said layer and at least one aggregate of cells fuses with at least one other aggregate of plurality of cells;
- Group II consisting of Claims 2-4 drawn to another method, wherein the matrix layer constitutes a first layer, the plurality of cell aggregates constitutes a first plurality of cell aggregates and predetermined pattern constitutes a first pattern, said method further comprises depositing a second layer of the matrix on the first layer and embedding a second plurality of cell aggregates in the second layer to form a second predetermined pattern and further allowing at least one aggregate of cells in the first layer to fuse with at least one aggregate of plurality of cells in the second layer; and
- Group III, consisting of claims 52-66, drawn to a three dimensional layered structure comprising at least one layer of a biocompatible matrix and a plurality of cell aggregates, each cell aggregate comprising a plurality of living cells, wherein cell aggregates are embedded in the at least one layer of biocompatible matrix in a pre-determined pattern.

### **Inventions are Independent or Distinct**

8. The inventions listed in Groups I-III *supra* do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The patent rules under 37 C.F.R. §1.475 for Unity of Invention (Paragraphs (a), (b) and (c)) are cited below:

#### **§1.475 Unity of Invention before the International Searching Authority, the International Preliminary Examining Authority and during the National Stage**

- (a) An International and National Stage Application shall relate to one invention only, or to a group of inventions so linked as to form a general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the

requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as whole, makes over the prior art.

(b) An International or a National stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

Inventions described in Groups I-III *supra* fall within category (2), methods and a product, wherein the two methods have different steps to make a product, i.e., composition.

9. PCT Rule 13.2 does not provide for multiple compositions, or multiple methods of making a composition, or multiple methods of use of a composition within a single application. Thus, the first appearing composition is combined with a corresponding first method of making said composition (if applicable) and/ or use of said composition. However, the additional composition and method claims each constitute a separate inventive Group.

In addition to the requirement that a Group of inventions must belong to one of the specific categories provided by PCT Rule 13.2, the inventions in the category, e.g., as a composition and a method of use of said composition, must have a special technical feature that unites them. See Patent rules under 37 C.F.R. §1.475, where a special technical feature is a contribution OVER THE PRIOR ART.

The special technical feature of each of Groups I and II methods is to make a certain product wherein only one layer of matrix is laid on a substrate in Group II and 2 layers are laid in Group II, Said method is well known in the relevant art e.g., Koibuchi et al (1999. Behavior of

cells in artificially made cell aggregates and tissue fragments after grafting to developing hind limb buds in ***Xenopus laevis***, **International Journal of Developmental Biology, Volume 43, Pages 141-148**) teach a method to implant cell aggregates made of dissociated mesenchymal cells from two different origins in different positions and stages of limb buds or grafted on limb stumps made by cutting on the limbs of ***Xenopus laevis*** (See for e.g., Abstract, Lines 6-16 and Figure 1). The substrate in this instance is the limb area itself or the materials where the cell aggregates were placed prior to implanting the structures in to the limb area (Page 142, Lines 8-14 under Figure 1; Page 142, Column 2, Lines 2-42; Figure 2 and Figure 3) to which the cell aggregates were implanted. After the cell growth, when implant of the three dimensional materials were made into the limbs (Page 142, Column 1, Lines 8-14 under Figure 1; Page 142, Column 2, Lines 2-16), the cell aggregates segregated to result in to the limb buds (Page 142, Column 2, Lines 17-42; Figures 2-3). Please note also that the cells were mesenchymal that resulted in to the mesodermal tissue (Thus the 3-dimensional structure). Libera et al (US Patent Application Publication 2003/0153078 A1 published 14 August 2003) also teach similar methods and compositions (Abstract, Example 3).

Thus as illustrated *supra*, the special technical features of inventive Groups I- III are well documented in the pertinent prior art. Consequently, the inventions instantly presented in Groups I-III do not make a contribution over the prior art and hence no special technical features exist among the inventions of Groups I-III.

Since no special technical feature exists among each of the inventions in Groups I-III, and because the special technical features of each of Group I-III inventions is not a contribution over the prior art, there is no unity of invention.

10. In accordance with 37 C.F.R. §1.499, applicant (S) is/are required, in response to this action, to elect a single invention to which the claims must be restricted.

Applicant(s) is/are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 C.F.R. §1.143).

11. Applicant (s) is/are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in

the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(i).

12. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. §1.116; amendments submitted after allowance are governed by 37 C.F.R. §1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. §1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §101, §102, §103, and §112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. §804.01.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:00 A.M. to 5:30 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

/Kailash C Srivastava/  
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